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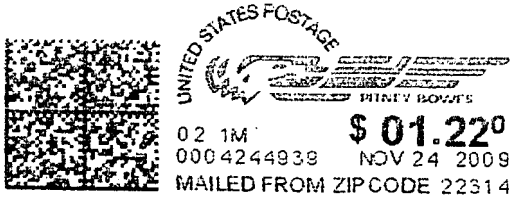

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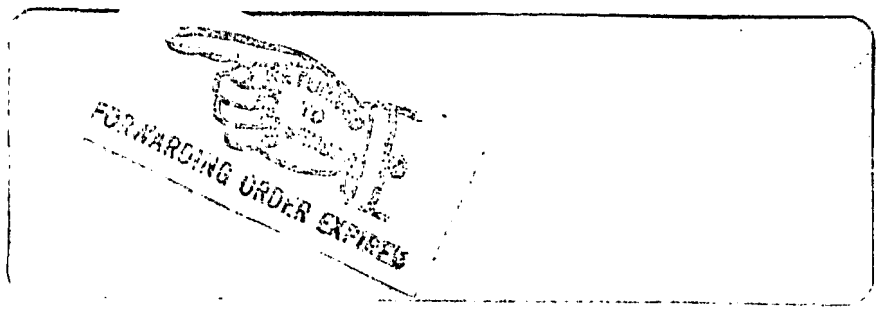

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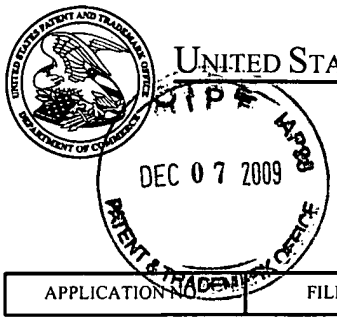

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,992	02/14/2001	Fabrizio Giannotta	VANM201.001A	2010

7590 11/24/2009

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620 Newport Center Drive
Newport Beach, CA 92660

EXAMINER	
EPPS -SMITH, JANET L	
ART UNIT	**PAPER NUMBER**
1633	

MAIL DATE	DELIVERY MODE
11/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/762,992	GIANNOTTA ET AL.	
	Examiner	Art Unit	
	Janet L. Epps-Smith	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24 and 26* is/are rejected.

7)☒ Claim(s) *25* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 February 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6-18-01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (Written Description/New Matter).

3. The methodology for determining adequacy of Written Description to convey that applicant was in possession of the claimed invention includes determining whether the application describes an actual reduction to practice, determining whether the invention is complete as evidenced by drawings or determining whether the invention has been set forth in terms of distinguishing identifying characteristics as evidenced by other descriptions of the invention that are sufficiently detailed to show that applicant was in possession of the claimed invention (Guidelines for Examination of Patent Applications under 35 USC § 112, p 1 "Written Description" Requirement; (Federal Register/Vol 66. No. 4, Friday, January 5, 2001; II Methodology for Determining Adequacy of Written Description (3.)).

4. The instant claims are drawn to genus of isolated polynucleotides which control the expression of a xylanase promoter-operator nucleotide sequence in trans,

comprising "at least about 100 nucleotides of SEQ ID NO: 1, its complement, or a homolog, wherein said homolog controls the expression of said xylanase promoter-operator."

5. First it is noted that the phrase "at least about 100 nucleotides" was not found in the specification as filed. Therefore applicants have not defined which at least about 100 nucleotides of SEQ ID NO: 1 actually possess the recited function of having the ability to control the expression of a xylanase promoter-operator. It is also noted that the phrase "control" includes within its context the ability to both induce and repress the expression of a xylanase promoter-operator.

6. With the exception of the full length nucleotide sequences of SEQ ID NO: 1 or the smaller sequence of SEQ ID NO: 3, there are no other nucleotide sequences described in the specification as filed that disclosed as having the ability to encode a peptide or peptidic sequence that controls the expression of a xylanase promoter-operator nucleotide sequence. SEQ ID NO: 4 is disclosed in the sequence listing as a nucleotide sequence, however the exact nature of this sequence is unclear since the specification as describes SEQ ID NO: 4 as a pUC18 polylinker on page 12 of the Specification as filed. However, on page 6 of the specification, SEQ ID NO: 4 is described as an amino acid sequence that comprises at least the amino-acid sequence encoded by the nucleotide sequence of SEQ ID NO: 3. In one aspect of the specification it suggests that SEQ ID NO: 4 is a nucleotide sequence (page 12), however in another embodiment it states the SEQ ID NO: 4 is an amino acid sequence.

7. Furthermore, there is no guidance to the ordinary skilled artisan that would suggest which sequences within the nucleotide sequences of either SEQ ID NO: 1 or 3 could be modified either by deletion and/or insertion such that the sequences would still maintain the ability to produce an amino acid sequence that would function to control the expression of a xylanase promoter-operator. There is no specific guidance in this regard. The skilled artisan would have to resort to de novo trial and error experimentation to identify those nucleotide structures as set forth in the instant claims that possess the ability to control the expression of a xylanase promoter-operator sequence in trans, wherein control includes both the ability to induce or repress the expression of said xylanase promoter-operator.

8. Thus, in view of the need for further experimentation to identify the structures of the claimed invention, particularly those that possess any 100 nucleotides of SEQ ID NO: 1, and still maintain the claimed function, it is concluded that Applicants were not in possession of the full scope of the claimed invention at the time of filing.

9. The Revised Interim Guideline for Examination of Patent Applications under 35 USC § 112, pl "Written Description" Requirement (Federal Register/Vol 66. No 4,. Friday January 5, 2001) states "THE CLAIMED INVENTION AS A WHOLE MAY NOT BE ADEQUATELY DESCRIBED IF THE CLAIMS REQUIRE AN ESSENTIAL OR CRITICAL ELEMENT WHICH IS NOT ADEQUATELY DESCRIBED IN THE SPECIFICATION AND WHICH IS NOT CONVENTIONAL IN THE ART" (column 3, page 71434), "WHEN THERE IS SUBSTANTIAL VARIATION WITHIN THE GENUS, ONE MUST DESCRIBE A SUFFICIENT VARIETY OF SPECIES TO REFLECT THE VARIATION WITHIN THE GENUS", "IN AN UNPREDICTABLE ART, ADEQUATE WRITTEN DESCRIPTION OF A GENUS WHICH

EMBRACES WIDELY VARIANT SPECIES CANNOT BE ACHIEVED BY DISCLOSING ONLY ONE SPECIES WITHIN THE GENUS"- (column 2, page 71436, emphasis added).

10. Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "APPLICANT MUST CONVEY WITH REASONABLE CLARITY TO THOSE SKILLED IN THE ART THAT, AS OF THE FILING DATE SOUGHT, HE OR SHE WAS IN POSSESSION OF THE INVENTION. THE INVENTION IS, FOR PURPOSES OF THE 'WRITTEN DESCRIPTION' INQUIRY, WHATEVER IS NOW CLAIMED." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize the [he or she] invented what is claimed." (See Vas-Cath at page 1116).

11. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. In Fiddes, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

12. See also MPEP § 2163, which states "[A] biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence."

13. Considering the potentially large numbers of compounds encompassed by these claims, the disclosure is not sufficient to show that a skilled artisan would recognize that the applicant was in possession of the claimed invention (genus) commensurate to its scope at the time the application was filed.

Claim Rejections - 35 USC § 112

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

16. Claim 26 recites "the isolated polynucleotide of claim 5 comprising SEQ ID NO: 4." This phrase is vague and indefinite since the nature of this sequence is unclear, as stated above, in one aspect of the specification it suggests that SEQ ID NO: 4 is a nucleotide sequence (page 12), however in another embodiment it states the SEQ ID NO: 4 is an amino acid sequence.

Claim Objection

17. Claim 25 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Smith whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Smith/
Primary Examiner, Art Unit 1633

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(USE SEVERAL SHEETS IF NECESSARY)

ATTY. DOCKET NO.	APPLICATION NO.
VANM201.001APC	09/762,992

APPLICANT	
Giannotta, et al.	
FILING DATE	GROUP
February 14, 2001	1632

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (IF APPROPRIATE)

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO

EXAMINER INITIAL		OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)
/J.E./	1	Van Peij et al., *Isolation and analysis of xlnR, encoding a transcriptional activator co-ordinating xylanolytic expression in Aspergillus niger*, MOLECULAR MICROBIOLOGY, Vol. 27, No. 1, January 1998, pp. 131-142.
/J.E./	2	Giannotta, F. et al., *A sequence-specific DNA-binding protein interacts with the xlnC upstream region of Streptomyces sp. strain EC3*, FEMS MICROBIOLOGY LETTERS, Vol. 142, 1996, pp. 91-97.
/J.E./	3	Accession No. Z19589, Hagege, J.M., *S.ambofaciens plasmid pSAM2 gene encoding KorSA*, Database Online, April 7, 1998.
/J.E./	4	International Search Report from Priority Application No. PCT/BE99/00105 dated December 8, 1999

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EXAMINER	/Janet Epps Smith/	DATE CONSIDERED	11/12/2009

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